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PATENT

Inventor: Marcus A. Horwitz

Serial No.: 10/695,155 Filing Date: 10/27/2003

Title: ABUNDANT EXTRACELLULAR

PRODUCTS AND METHODS FOR THEIR PRODUCTION AND USE

Examiner: Unassigned

Group Art Unit: 1641

Atty Docket No.: 51326-00004

CERTIFICATE OF EXPRESS MAIL EV 276062938 US

I hereby certify that on _______, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage to in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Maria Nadal

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. §§ 1.56. 1.97 and 1.98, and in accordance with the provisions in the Manual of Patent Examining Procedure §§609 and 707.05(b), enclosed is a copy of the substitute for Form PTO-1449 listing the references that are known to applicant. Applicants enclose copies of each of the listed references which are not U.S. patents.

This art is being filed for consideration in compliance with § 1.97 within the following time period:

37 C.F.R. § 1.97(b)(3) This information is being filed for consideration and entry before the mailing of a first Office Action on the merits.

Applicant: Marcus A. Horwitz

PATENT

Opicial No. : 10/605-155

Docket No. 51326-00004

Serial No.: 10/695,155 Group Art Unit: 1641

The submission of the above-described documents does not constitute an admission nor should it be construed as a representation that: a search has been made, or that it is material to patentability as defined in § 1.56(b).

Applicant reserves the right to antedate or otherwise remove the documents as references.

It is respectfully requested that the listed references be considered in the examination of this application and identified on the list of references cited on the patent issuing for this application. Applicant also requests that an initialed copy of the substitute for Form PTO-1449 be entered in the application file and returned to applicant with the next communication from the Office in accordance with MPEP § 609.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application Applicants believe no fee is due with this filing, however, if it is deemed that a fee is due, the Director is hereby authorized to charge any fees or credit any overpayments to Deposit Account No. 50-3207 associated with this response.

Respectfully submitted,

Dated: 12/30/04

Louis C. Cullman by Hicherle glasky Louis C. Cullman

Registration No. 39,645

PRESTON GATES & ELLIS LLP 1900 Main Sreet, Suite 600 Irvine, California 92614-7319 Telephone: (949) 253-0900 Facsimile: (949) 253-0902

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number 10/695,155

Filing Date 10/27/2003

First Named Inventor Marcus Horwitz

Group Art Unit 1641

Examiner Name Unassigned

Complete if Known

(use as many sheets as necessary)

6 1449A/PTO

Sheet 1 of 12 Attorney Docket Number 51326-00004

			U.S. PATENT DOCUME	NTS	
Examiner Initials	Cite No.1	Document Number Number-Kind Code ^{2 (if known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		3,888,837	06/10/75	Tsumita et al.	
*****		3,943,119	03/09/76	Tsumita et al.	
		4,123,427	10/31/78	Dniel	
		4,285,931	08/25/81	Limjuco et al.	
		4,460,503	07/17/84	Savrda et al.	
		4,724,144	02/09/88	Rook et al.	
		4,777,130	10/11/88	Maes	
		4,889,800	12/26/89	Shinnick et al.	
		4,906,742	03/06/90	Young et al.	
***		4,952,395	08/28/90	Shinnick et al.	
		4,965,192	10/23/90	Maes	
		4,976,958	12/11/90	Shinnick et al.	
····		5,108,745	04/28/92	Horwitz	
		5,154,923	10/13/92	Van Eden et al.	
	1	5,169,940	12/08/92	Patarroyo	
	İ	5,171,839	12/15/92	Patarroyo	
		5,225,324	07/06/93	McFadden et al.	
		5,254,459	10/19/93	Patarroyo	
		5,268,170	12/07/93	Van Eden et al.	

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		Foreign Patent Document				Pages, Columns, Lines, Where		
Examiner Initials	Cite No.1	Office ³	Number ⁴	Kind Code⁵	Date of Publications of Cited Documents MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	T ⁶
		EP	0499003	A1	08/1992	N.V. Immunogenetics S.A.		
		EP	0519218		12/1992	Biotechnologische Forschung mbH		
		GB	2239246		06/1991	Aktiebolaget Astra		
		wo	85/03639		08/1985	University College London		
		WO	88/02027		03/1988	Applied Biotechnology, Inc.		
		wo	88/05823		08/1988	Whitehead Institute for Biomedical Research		
		wo	88/06626		09/1988	Whitehead Institute for Biomedical Research		
Examiner			-			Date Considered		

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STATEMENT BY APPLICANT

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Sheet

Application Number	10/695,155	
Filing Date	10/27/2003	
First Named Inventor	Marcus Horwitz	
Group Art Unit	1641	
Examiner Name	Unassigned	· · · · · ·
Attorney Docket Number	51326-00004	

				FOREIG	N PATENT DOCUME	NTS		
Examiner	Cite	Fo Office ³	Foreign Patent Document Office ³ Number ⁴ Kind Code ⁵		Date of Publications of Cited Documents	Name of Patentee or Applicant of Cited	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures	T⁵
					MM-DD-YYYY	Document	Appear	
		WO	89/05825		06/1989	Immunex Corp.		<u> </u>
		WO	89/12455		12/1989	Whitehead Institute for Biomedical Research		
		wo	90/00594		01/1990	Whitehead Institute for Biomedical Research		
		WO	90/02564		03/1990	Codon		
		wo	90/10449		09/1990	Cohen IR et al.		
		wo	90/15873		12/1990	Whitehead Institute for Biomedical Research		
		WO	91/04272		04/1991	N.V. Immunogenetics S.A.		ļ
	1	wo	91/14448	i i	10/1991	Aktiebolaget Astra		
		WO	92/01783		02/1992	Albert Einstein College of Medicine		
		wo	92/01796		02/1992	Smith-Kline Beecham Biologicals		
		wo	92/04462		03/1992	Immunologic Pharma.		
		wo	92/16628		10/1992	N.V. Immunogenetics S.A.		
		wo	92/21376		12/1992	Medimmune Inc.		
		wo	92/21697		12/1992	Medical Research Council		
		wo	92/22326		12/1992	Albert Einstein College of Medicine		
		wo	93/07897		04/1993	Medimmune Inc.		
		wo	93/14118		07/1993	Medical Research Council		
		wo	93/14789		08/1993	New England Medical Center Hospitals, Inc.		
		wo	94/02508		02/1994	Proteus Molecular Design Ltd.		
		wo	95/01440		01/1995	Statenserum Institut		
		wo	95/01441		01/1995	Statenserum Institut		
		wo	95/14713		06/1995	Regents of the University of California		

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Signature	Co	onsidered	

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449A/PTO Complete if Known 10/695,155 Application Number INFORMATION DISCLOSURE Filing Date 10/27/2003 First Named Inventor Marcus Horwitz STATEMENT BY APPLICANT 1641 **Group Art Unit** Unassigned **Examiner Name** (use as many sheets as necessary) 51326-00004 12 Sheet of Attorney Docket Number

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
		C. Abou-Zeid et al., "The Secreted Antigens of Mycobacterium tuberculosis Available Antibodies," 1988, 134:531-538, J. Gen. Micro.	
		C. Abou-zeid et al., "Characerization of Fibronectin Mycobacterium bovis BCG," Dec. 1988, 56(12):3046-3051, Infection and Immunity.	
		C. Abou-zeid et al., "Genetic and Immunological Analysis Fibronectin-Binding Proteins," Aug. 1991, 59(8):2712-2718, Infection and Immunity.	
		E. Adams et al., "T cell reactivity household contacts," 1990, 80:206-212, Clin. Exp. Immunol.	
		Allison, A.C. and N.E. Byars. "An adjuvant formulation that selectively elicits the formation of antibodies of protective isotypes and of cell-mediated immunity," J. Immunol. Meth. 95:157-68, 1986	
	:	Andersen, P., and I Heron. "Specificity of a Protective Memory Immune Response against Mycobacterium tuberculosis." Infection and Immunology 61 (1993) 844-51.	
		Belisle, J. T., et al. "Identification of a Mycolyltransferase from Mycobacterium tuberculosis and the Coincident Definition of the Physiological Function of Antigen 85B." In the program from the Thirtieth U.SJapan Tuberculosis Research Conference, Leprosy Research Conference and Tuberculosis/Leprosy Symposium. U.SJapan Cooperative Medical Science Program. Ft. Collins, Colorado (Jul. 19-21, 1995) 212-6.	
		Berdal, Bjorn P., et al. "Demonstration of Extracellular Chymotrypsin-Like Activity from Various Legionella Species." Journal of Clinical Microbiology 16 (Sep. 1982) 452-7.	
		V. Bhardwaj & M.J. Colston, "The processiong and presentation of mycobacterial monocytes," 1988, 18:691-696, Eur. J. Immunol.	
		S.J. Blander & M.A. Horwitz, "Vaccination with the Major Secretory Protein Legionnaires' Disease," Mar. 1989, 169:691-705, J. Exp. Med.	
		Blander, Steven J., et al. "A Live Avirulent Mutant Legionella pneumophila Vaccine Induces Protective Immunity against Lethal Aerosol Challenge." J. Clin. Invest. 83 (Mar. 1989) 810-5.	
		Blander, Steven J., et al. "An Immunoprotective Molecule, the Major Secretory Protein of Legionella pneumophila, Is Not a Virulence Factor in a Guinea Pig Model of Legionnaires' Disease." Journal of Clinical Investigation 86 (Sep. 1990) 817-24.	
		Blander, Steven J., and Marcus A. Horwitz. "Vaccination with Legionella pneumophila Membranes Induces Cell-mediated and Protective Immunity in a Guinea Pig Model of Legionnaires' Disease." Journal of Clinical Investigation 87 (Mar. 1991 1054-9.	
		Blander, Steven J., and Marcus A. Horwitz. "Vaccination with the Major Secretory Protein of Legionella Induces Humoral and Cell-mediated Immune Responses and Protective Immunity across Different Serogroups of Legionella pneumophila and Different Species of Legionella." Journal of Immunology 147 (Jul. 1991) 285-91.	

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Sheet

Application Number	10/695,155
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First Named Inventor	Marcus Horwitz
Group Art Unit	1641
Examiner Name	Unassigned
Attorney Docket Number	51326-00004

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Blander, Steven J., and Marcus A. Horwitz. "Major Cytoplasmic Membrane Protein of Legionella pneumophila, a Genus Common Antigen and Member of the hsp 60 Family of Heat Shock Proteins, Induces Protective Immunity in a Guinea Pig Model of Legionnaires' Disease." Journal of Clinical Investigation 91 (Feb. 1993) 717-23.	
		Bloch, Hubert, and William Segal. "Viability and Multiplication of Vaccines in Immunization Against Tuberculosis." American Review of Tuberculosis 7(1955) 228-48.	
		B.R. Bloom et al., "Genes for the protein antigens of the tuberculosis and leprosy bacilli," 1985, 5:839-845, Science Reports.	
		Bloom, Barry R. "New Approaches to Vaccine Development." Reviews of Infectious Disease, 1989, 11(2): S460-6.	
		Borremans et al., "Cloning, sequence determination, and expression of a 32-kilodalton-protein gene of Mycobacterium tuberculosis," Infect. Immun. 57(10):3123-30, 1989.	
		Brennan, Patrick J. "Structure of Mycobacteria: Recent Developments in Defining Cell Wall Carbohydrates and Proteins." Reviews of Infectious Disease, 1989, 11(2): S420-30.	
		R.F. Breiman & M.A. Horwitz, "Guinea Pigs Sublethally Infected Challenge," Mar. 1987, 164:799-811, J. Exp. Med.	
		W.J. Britton et al., "Immunoreactivity of a 70 kD Protein Chromatography," Sep. 1986, 691-708, J.Exp.Medicine.	
		K.M. Citron, "Control and prevention of tuberculosis in Britain," 1988, 44(3):704-716, Br. Med. Bull.	
		Chen, E. Y., and P. H. Seeburg. "Supercoil Sequencing: A Fast and Simple Method for Sequencing Plasmid DNA." DNA 4 (1985) 165-70.	
		Collins, et al., "Biological activity of protein antigens isolated from Mycobacterium tuberculosis culture filtrate," Infect. Immun. 1988, vol. 56(5), 1260-1266.	
		Clemens, D. L., and M. A. Horwitz. "Characterization of the Mycobacterium tuberculosis Phagosome and Evidence That Phagosmal Is Inhibited." Journal of Experimental Medicine 181 (1995) 257-70.	
		G.W. Comstock, "Identification of an Effective Vaccine Against Tuberculosis," 1988, 138:479-480, Am. Rev. Respir. Dis.	
		J. Content et al., "The Genes Coding for the Antigen 85 Complexes M. tuberculosis," Sep. 1991, 59(9):3205-3212, Infection and Immunity	
		A.J. Crowle, "Immunization against Tuberculosis: What Kind of Vaccine?" Nov. 1988, 56(11):2769-2773, Infection and Immunity.	
		Daniel, Thomas M. "Rapid Diagnosis of Tuberculosis: Laboratory Techniques Applicable in Developing Countries." Reviews of Infectious Disease, 1989, 11(2): S471-8.	
		Dannenberg, Arthur M., Jr. "Immune Mechanisms in the Pathogenesis of Pulmonary Tuberculosis." Reviews of Infectious Disease, 1989, 11(2): S369-78.	

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		NON PATENT LITERATURE DOCUMENTS	
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		De Vries, Rene R.P. "Regulation of T Cell Responsiveness Against Mycobacterial Antigens by HLA Class 2 Immune Response Genes." Reviews of Infectious Disease, 1989, 11(2): S400-3.	
		A. Drowart et al., "Isoelectrophoretic Characterization of Protein Antigens Antigen 85 Complex," 1992, 36:697-702, Scand. J. Immunol.	
		Dubos, Rene J., et al. "Antituberculosis Immunity Induced in Mice by Vaccination with Living Cultures of Attenuated Tubercle Bacilli." Journal of Experimental Medicine 97 (1953) 207-20.	
		H.D. Eberhard, "Leser-ZuchriftenTuberkulose-Schutzimpfung," 1982, 1821-1822, Dtsch. med. Wschr.	
•		Ellner, Jerrold J. and Robert S. Wallis. "Immunologic Aspects of Mycobacterial Infections." Reviews of Infectious Disease, 1989, 11(2): S455-9.	
•		F. Emmrich et al., "A Recombinant 64 Kilodalton Protein Mycobacterial Antigens," Apr. 1986, 163:1024-1029, J. Exp. Med.	
		Feller, D. C., and V. F. de la Cruz. "Identifying Antigenic T-Cell Sites." Nature 349 (1991) 720-1.	
		P.E.M. Fine et al., "The relationship between delayed type hypersensitivity mycobacterial vaccines in man," 1986, 57:275-283, Lepr.Rev., Suppl. 2.	
		P.E.M. Fine, "BCG vaccination against Tuberculosis and leprosy," 1988, 44:691-703, Br. Med. Bull.	
		Fine, Paul E.M. "The BCG Story: Lessons from the Past and Implications for the Future." Reviews of Infectious Disease, 1989, 11(2): S353-9.	
		E. Freerksen, "Kommentare Tuberkulose-Schutzimpfung," 1982, 1564-1569, Dtsch. med. Wschr.	
		R.J. Garsia et al., "Homology of the 70-Kilodalton Antigens Eucaryotes," Jan. 1989, 57(1):204-212, Infection and Immunity.	
		H.P. Godfrey et al., "Modulation of Expression Fibronectin-Binding Proteins," Jun. 1992, 60(6):2522-2528, Infection and Immunity.	
		J.M. Grange, "Molecular Biology: New Hopes and Challenges," 1988, 69:1-4, Tubercle.	
		Grossett, Jacques H. "Present Status of Chemotherapy for Tuberculosis." Reviews of Infectious Disease, 1989, 11(2): S347-52.	
		Grunstein, M., and D. S. Hogness. "Colony Hybridization: A Method for the Isolation of Cloned DNAs That Contain a Specific Gene." Proc. Natl. Acad. Sci. USA 72 (1975) 3961-6.	
		H. Hahn, "Antibacterial Defence Mechanisms," 1983, S112-S121, Infection II (1983) Suppl. 2.	
		Harth, Gunter, et al. "Glutamine Synthetase of Mycobacterium tuberculosis: Extracellular Release and Characterization of Its Enzymatic Activity." Proc. Natl. Acad. Sci. USA 91 (1994) 9342-6.	
		Hatfull, G. F., and G. J. Sarkis. "DNA Sequence, Structure and Gene Expression of Mycobacteriophage L5: A Phage system for Mycobacterial Genetics." Mol. Micro. 7 (1993) 395-405.	

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		D.V. Havlir et al., "Human Immune Response to Mycobacterium tuberculosis Antigens," Feb. 1991, 59(2):665-670, Infection and Immunity.	
		Heym et al., "Characterization of the katG gene encoding a catalase-peroxidase required for the isoniazid susceptibility of Mycobacterium tuberculosis," J. Bacteriol. 1993, vol. 175(13), 4255-4259.	
		Horwitz, Marcus A., and Samuel C. Silverstein. "Legionnaires' Disease Bacterium (Legionella pneumophila) Multiplies Intracellularly in Human Monocytes." Journal of Clinical Investigation 66 (Sep. 1980) 441-50.	
		Horwitz, Marcus A. "Cell-mediated Immunity in Legionnaires' Disease." Journal of Clinical Investigation 71 (Jun. 1983) 1686-97.	
		Horwitz, Marcus A. "Characterization of Avirulent Mutant Legionella pneumophila that Survive but do not Multiply with Human Monocytes." J. Exp. Med. 166 (Nov. 1987) 1310-28.	
		M.A.Horwitz, "Intracellular parasitism," 1988, 1:41-46, Current Opinion in Immunology.	
		M.A. Horwitz, "The Immunobiology of Legionella pneumophila," Chapter 11, 1989, 141-156, Intracellular Parasitism.	
		Horwitz, Marcus A., et al. "Progress in the Development of a Subunit Vaccine Against Tuberculosis." From the Twenty-Ninth U.SJapan Leprosy Research Conference, Tuberculosis Research Conference, and Leprosy/Tuberculosis Symposium (Aug. 19-22, 1994).	
		Horwitz, Marcus A., et al. "Protective Immunity Against Tuberculosis Induced by Vaccination with Major Extracellular Proteins of Mycobacterium tuberculosis." Proc. Natl. Acad. Sci. USA 92 (1995) 1530-34.	
		Horwitz, Marcus A., et al., "Progress in the Development of a Subunit Vaccine against Tuberculosis and a New Nonhuman Primate Model of Pulmonary Tuberculosis," Journal of Cellular Biochemistry, Supplement O (19B), Feb. 1995, p. 60, Abstract No. B3-014.	
		Huygen, Kris, et al. "Specific Lymphoproliferation, Gamma Interferon Production, and Serum Immunoglobulin G Directed against a Purified 32 kDa Mycobacterial Protein Antigen (P32) in Patients with Active Tuberculosis." Scandinavian Journal of Immunology 27 (1988) 187-94.	
		Huygen, Kris, et al. "Immunogenicity of a Tuberculosis DNA Vaccine Containing Genes Encoding the Components of the Secreted Antigen 85 Complex." Journal of Cellular BiochemistryMolecular Mechanisms in Tuberculosis from the Keystone Symposia on Molecular & Cellular Biology, Supplement 19B, 1995 (Feb. 5-Mar. 15, 1995) Abstract No. B3-408.	
		Jacobs, William R., Jr., et al. "Mycobacteriophage Vector Systems." Reviews of Infectious Disease, 1989, 11(2): S404-10.	
		W.S. Jordan, Jr., "Impediments to the Development of Additional Vaccines Next Decade," May-Jun. 1989, II(Supp.3):S603-612, Rev. Infec. Diseases.	

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Signature	Co	nsidered	

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Sheet	7	of	12	Attorney Docket Number	51326-00004			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		S.H.E. Kaufmann, "T Cell Clones and their Products: Infections," 1985, S177-S182, Infection 13 Suppl.2.	
		S.H.E. Kaufmann & D.B. Young, "Vaccination against Tuberculosis and Leprosy," 1992, 184:208-229, Immunobiol.	
		Kaufman, Stefan H.E. "In Vitro Analysis of the Cellular Mechanisms Involved in Immunity to Tuberculosis." Reviews of Infectious Disease, 1989, 11(2): S448-54.	
		Kingston et al., "Immunological activity of a 14-kilodalton recombinant protein of Mycobacterium tuberculosis H37Rv," Infect. Immun. 1987, vol. 55(12), 3149-3154.	
		Kitaura, H., et al. "Cloning, Sequencing and Expresssion of the Gene for Alpha Antigen from Mycobacterium intracellulare and Use of PCR for the Rapid Indentification of Mycobacterium intracellulare." Biochemical and Biophysical Research Communications 196 (1993) 1466-73.	
		Kiyotani, K., et al., "Mycobacterial Lipase Inhibitor: A New Lipase Inhibitor Isolated from Culture Filtrate of Mycobacterium tuberculosis," Chemical Abstracts, vol. 100, No. 23, Jun. 4, 1984, p. 252, col. 1, Abstracts No. 187918d.	
		E. Krambovitis, "Detection of antibodies to Mycobacterium tuberculosis plasma assay," 1986, 21:257-264, Med. Microbiol.	
		Kremer, L., et al. "Analysis of the Mycobacterium tuberculosis 85A Antigen Promoter Region." Journal of Bacteriology 177 (1995) 642-53.	
		Kubica, George P., and Lawrence G. Wayne, eds. The Mycobacteria: A Sourcebook. 2 parts. New York: Marcel Dekker, Inc. 33-57.	
		Kyte, J., R. F. Doolittle. "Simple Method for Displaying the Hydropathic Character of a Protein." Journal of Molecular Biology 157 (1982) 105-32.	
		F.M. LaForce, "Immunizations, Immunoprophylaxis Infections," May 8, 1987, 257(18):2464-2470, JAMA.	
		P.H. Lagrange et al., "Immunological Mechanisms Controlling Mycobacterial Infections," 1983, 163-172, Bull. Europ. Physiopath. Resp.	
		Lamb, Jonathan R., et al. Identification of Mycobacterial Antigens Recognized by T Lymphocytes. Reviews of Infectious Disease, 1989, 11(2): S443-7.	
		P. Launois et al., "T cell response in leprosy patients," 1991, 86:286-290, Clin. Exp. Immunol.	
		P. Launois et al., "IL-6 Production in Response to Purified Mycobacterial Heat-Shock Protein Leprosy," 1993, 148:283-290, Cellular Immunology.	
		Launois, P., et al. "T-Cell-Epitope Mapping of the Major Secreted Mycobacterial Antigen Ag85A in Tuberculosis and Leprosy." Infection and Immunity 62 (1994) 3679-87.	
		Lee, Bai-Yu, et al., "Characterization of the Major Membrane Protein of Virulent Mycobacterium tuberculosis," Infection and Immunity, vol. 60, No. 5, May 1992, pp. 2066-2074.	

Examiner	Date	
Signature	Considered	

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		NON PATENT LITERATURE DOCUMENTS	1
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		Lee, Byong-Wha Esther, et al. "Cell-Mediated Immune Responses to the Native 71kD Protein of	
		Mycobacterium tuberculosis in Guinea Pigs and Humans." From the Twenty-Seventh U.SJapan	
	:	Leprosy Research Conference, Tuberculosis Research Conference, And Leprosy/Tuberculosis Symposium (Aug. 4-7, 1992).	
		Lee, BY., and M. A. Horwitz. "Identification of Macrophage and Stress-Induced Protein of	1
		Mycobacterium tuberculosis." Journal of Clinical Investigation 96 (1995) 245-9.	<u> </u>
		Lee, T. D., and S. Vemuri. "MacProMass: A Computer Program to Correlate Mass Spectral Data to Peptide and Protein Structures." Biomed. Environmental Mass Spectroscopy 19 (1990) 639-45.	
		B.J. Luft et al., "Immunologic and Structural Characterization Borrelia burgdorferi," Apr. 15, 1991, 146(8):2776-2782, Journal of Immunology.	
-		K. Matsuo et al., "Cloning and Expression of the Mycobacterium bovis Antigen," Sep. 1988, 170(9):3847-3854, Journal of Bacteriology.	
		Maugh, Thomas H., 2d. "Promising Tests Reported for New TB Vaccine." Los Angeles Times, Feb. 28, 1995, p. 1, col. 3.	
		K.R. McKenzie et al., "Sequence and Immunogenicity Mycobacterium leprae," Jul. 1, 1991, 147(1):312-319, Journal of Immunology.	
		L. de Mendonca Lima, "Nucleotide sequence of the gene coding Mycobacterium leprae," 1991, 19(20):5789, Nucleic Acids Research.	
		A.Mehlert & D.B.Young, "Biochemical and antigenic heat-shock protein family," 1989, 3(2):125-130, Molecular Microbiology.	
		Meyer, Sven Nissen. "Animal Studies on Effects of BCG, H37Ra and Mycobacterium phlei in Tuberculosis Immunization." Tubercle 37(Jan-Feb 1956) 11-12.	
		Muller, Hans E. "Proteolytic Action of Legionella pneumophila on Human Serum Proteins." Infection and Immunity 27 (Jan. 1980) 51-3.	
		Munk, et al., "T cell responses of normal individuals towards recombinant protein antigens of Mycobacterium tuberculosis," Eur. J. Immunol. 1988, vol. 18, 1835-1838.	
		A.S. Mustafa et al. "Characteristics of human T-cell clones patients," 1986, 57:123-130, Symposium on the Immunology of Leprosy, Lepr. Rev. Suppl. 2.	
<u>-</u>		Myung, Seok J., et al., "Affinity Purification of Beta Antigen of Mycobacterium tuberculosis by Using	
		Specific Monoclonal Antibody and Its Application for the Diagnosis of Tuberculosis Meningitis by Elisa," Chemical Abstracts, vol. 112, No. 19, May 7, 1990, p. 534, col. 2, Abstract No. 176521r.	
		Nagai, Sadamu, et al., "Isolation and Partial Characterization of Major Protein Antigens in the Culture Fluid of Mycobacterium tuberculosis," Infect. Immun., vol. 59, No. 10, Oct. 1991, pp. 372-82.	
		Oettinger, Thomas, et al., "Cloning and B-Cell-Epitope Mapping of MPT64 from Mycobacterium tuberculosis H37Rv," Infection and Immunity, vol. 62, No. 5, May 1994, pp. 2058-2064.	

Examiner	Date	
Signature	Considered	

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STATEMENT BY APPLICANT			NT	First Named Inventor	Marcus Horwitz	
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		NON PATENT LITERATURE DOCUMENTS	
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		Ohara, Naoya, et al., "Cloning and Sequencing of the Gene for Alpha Antigene from Mycobacterium avium and Mapping of B-Cell Epitopes," Infect. Immun., vol. 61, No. 4, Apr. 1993, pp. 1173-1179.	
		I.M. Orme & F.M. Collins, "Infection with Mycobacterium kansasii and efficacy of vaccination against tuberculosis," 1983, 581-586, Immunology.	
		Ian M. Orme, "The Kinetics of Emergence and Loss Mycobacterium tuberculosis," Jan. 1, 1987, 138:293-298, J. Immunol.	
		1.M. Orme, "Characteristics and Specificity of Acquired Immunologic Memory to M. tuberculosis Infection," May 15, 1988, 140(10):3589-93, J. Immunology.	
		I.M. Orme, "Induction of Nonspecific Acquired Resistance Vaccines," Dec. 1988, 56(12):3310-3312, Infection and Immunity.	
		Orme, Ian M., et al. "T. Lymphocytes Mediating Protection and Cellular Cytolysis During the Course of Mycobacterium tuberculosis Infection." The Journal of Immunology 148 (Jan. 1992) 189-96.	
		P.G. Pal & M.A. Horwitz, "Immunization with Extracellular Proteins Pulmonary Tuberculosis," Nov. 1992, 60(11):4781-4792, Infection and Immunity.	
		Pal, Primepares G., et al., "Immunization with Extracellular Proteins of Mycobacterium tuberculosis Induces Cell-Mediated and Protective Immunity in a Guinea Pig Model of Pulmonary Tuberculosis," Clinical Research, vol. 39, No. 2, 1991, p. 174A.	
		Palmer, C., et al., "Experimental Studies of Vaccination, Allergy, and Immunity in Tuberculosis." Bulletin of the World Health Organization 12 (1955) 47-62.	
		Patel, Rubina J., et al. A Cloned DNA Fragment for Identification of Mycobacterium tuberculosis. Reviews of Infectious Disease, 1989, 11(2): S411-9.	
		P. Peake et al., "Mechanism of Interaction of the 85B Secreted Protein Fibronectin," Nov. 1993, 61(11):4828-4834, Infection and Immunity.	
		M.C.V. Pessolani & P.J. Brennan, "Mycobacterium leprae Produces Antigen 85 Complex," Nov. 1992, 60(11):4452-4459, Infection and Immunity.	
		Piessens, Willy F. "Introduction to the Immunology of Tuberculosis." Reviews of Infectious Disease, 1989, 11(2): S436-42.	
		Pio, Antonio. "Impact of Present Control Methods on the Problem of Tuberculosis." Reviews of Infectious Disease, 1989, 11(2): S360-5.	
		Parenti, Francesco. "New Experimental Drugs for the Treatment of Tuberculosis." Reviews of Infectious Disease, 1989, 11(2): S479-83.	
		Pribnow, D. "Nucleotide Sequence of an RNA Polymerase Binding Site at an Early T7 Promoter." Proceedings of the National Academy of Science USA 72 (1975) 784-8.	
		Quinn, Thomas C. "Interactions of the Human Immunodeficiency Virus and Tuberculosis and the Implications for BCG Vaccination." Reviews of Infectious Disease, 1989, 11(2): S379-84.	

Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). 'See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.4. 'Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 'For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent documents. 'Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 'Applicant is to place a check mark here if English language Translation is attached.

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		NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No.1							
		A.J. Radford et al., "Cloning of a Species-Specific Antigen of Mycobacterium bovis," Apr. 1988, 56(4):921-925, Infection and Immunity.						
		A. Rambukkana et al., "Identification and Characterization of Epitopes Mycobacterium leprae," Nov. 1992, 60(11):4517-4527, Infection and Immunity.						
		A. Rambukkana et al., "Heterogeneity of Monoclonal Antibody-React. Epitopes Cell Wall Surface," Dec. 1992, 60(12):5172-5181, Infection and Immunity.	-					
		A. Rambukkana et al., "The Mycobacterial Secreted Antigen 85 Armadillo Tissues," May 1993, 61(5):1835-1845, Infection and Immunity.						
		A. Rees et al., "Specificity of proliferative response mycobaterial antigens," 1988, 18:1881-1887, Eur. J. Immunol.						
		E. Ribi et al., "Induction of Resistance to Tuberculosis in Mice Unrelated Materials," 1982, 345-356, Zbl.Bakt.Hyg., I.						
	,	T.F. Rinke de Wit, "The Mycobacterium leprae Antigen 85 MPT51 Proteins," Sep. 1993, 61(9):3642-3647, Infection and Immunity.						
		Roche, Paul W., et al. "T-Cell Determinants and Antibody Binding Sites on the Major Mycobacterial Secretory Protein MPB59 of Mycobacterium bovis." Infection and Immunity 62 (Dec. 1994) 5319-26.						
		H.S.Rumschlag et al., "Serological Responses Mycobacterium tuberculosis," Oct. 1988, 26(10):2200-2202, J. Clin. Microbio.						
		Salata et al., "Purification and characterization of the 30,000 dalton native antigen of Mycobacterium tuberculosis and characterization of six monoclonal antibodies reactive with a major epitope of this antigen," J. Lab. Clin., Med. 1991, vol. 118. 589-598.						
		Sanger, F., et al. "DNA Sequencing with Chain-Terminating Inhibitors." Proceedings of the National Academy of Science USA 74 (1977) 5463-7.						
1		Sensi, Piero. "Approaches to the Development of New Antituberculosis Drugs." Reviews of Infectious Disease, 1989, 11(2): S467-70.						
		Shine, J., and L. Dalgarno. "The 3'-Terminal Sequence of Escherichia coli 16S Ribosomal RNA: Complementarily to Nonsense Triplets and Ribosome Binding Sites." Proc. Natl. Acad. Sci. USA 71 (1974) 1342-6.						
		Shinnick, T. M. "The 65-Kilodalton Antigen of Mycobacterium tuberculosis." J. Bacteriol. 169 (1987) 1080-8.						
		Silver, Richard F., "T-Cell Epitopes of the 39kD Alpha Antigen of Mycobacterium tuberculosis BCG: Potential for Use in Vaccines and Diagnosis." Journal of Cellular BiochemistryMolecular Mechanisms in Tuberculosis from the Keystone Symposia on Molecular & Cellular Biology, Supplement 19B, 1995 (Feb. 5Mar. 15, 1995) Abstract No. B3-336:94.						
		Skamene, Emil. "Genetic Control of Susceptibility to Mycobacterial Infections." Reviews of Infectious Disease, 1989, 11(2): S394-9.						
Examiner Signature		Date Considered	- 543					

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspin.gov or MPEP 901.4. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent documents. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

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		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No.1					
		Smith, Donald W., and Ernst H. Wiegeshaus. "What Animal Models Can TeachUs about the Pathogenesis of Tuberculosis in Humans." Reviews of Infectious Disease, 1989, 11(2): S358-93.				
		Stead, William W. "Pathogenesis of Tuberculosis: Clinical and Epidemiologic Perspective." Reviews of Infectious Disease, 1989, 11(2): S369-78.				
		Styblo, Karel. "Overview and Epidemiologic Assessment of the Current Global Tuberculosis Situation with an Emphasis on Control in Developing Countries." Reviews of Infectious Disease, 1989, 11(2): S339-46.				
		J.E.R. Thole et al., "Molecular and immunological analysis Mycobacterium leprae," 1992, 6(2):153-163, Molecular Microbiology.				
		M. Turneer et al., "Humoral Immune Response in Human Tuberculosis: Bacillus Calmette-Guerin," Sep. 1988, 26:1714-1719, J. Clin. Microbio.				
		Verbon et al., "Development of a serological test for tuberculosis", Nederlands Tijdschrift voor Geneeskunde, vol. 135, No. 4, pp. 134-138, Jan. 26, 1991.*				
		Verbon, Annelies, et al., "The 14,000-Molecular-Weight Antigen of Mycobacterium tuberculosis Is Related to the Alpha-Crystallin Family of Low-Molecular-Weight Heat Shock Proteins," Journal of Bacteriology, vol. 174, No.4, Feb. 1992, pp. 1352-1359.				
		Verbon, A., et al., "Characterization of B Cell Epitopes on the 16K antigen of Mycobacterium tuberculosis," Clin. Exp. Immunol., vol. 89, No. 3, 1992, pp. 395-401.				
		Von Heijne, G. "A New Method for Predicting Signal Sequence Cleavage Sites." Nucleic Acids Research 14 (1986) 4683-90.				
		Wallis, et al., "Identification by two-dimensional gel electrophoresis of a 58-kilodalton tumor necrosis factor-inducing protein of Mycobacterium tuberculosis," Infect. Immun. 1993, vol 61(2), 627-632.				
		Weiss, David W., "Vaccination Against Tuberculosis with Nonliving Vaccines", Jan. 15, 1959, pp. 340-358.				
		Weiss, David W., and A.Q. Wells. "Immunization with Dead Tubercle Bacilli." Tubercle 37 (Apr. 1956) 137-40.				
		Wiegeshaus, E.H., et al., "Evaluation of the protective potency of new tuberculosis vaccines", Reviews of Infectious Diseases, vol. II, Suppl. 2, pp. S484-S490, Mar. 1, 1989.				
		H.G. Wiker et al., "Evidence for Three Separate Genes Antigen 85 Complex," Jan. 1990, 58(1):272-274, Infection and Immunity.				
		H.G. Wiker et al., "Localization index for distinction Mycobacterium tuberculosis," 1991, 137:875-884, Journal of General Microbiology.				
		H.G. Wiker & M. Harboe, "The Antigen 85 Complex: a Major Secretion Product of M. tuberculosis," Dec. 1992, 56(4):648-661, Microbiological Reviews.				

Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *Applicant's unique citation designation number (optional). *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.4. *Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent documents. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. *Applicant is to place a check mark here if English language Translation is attached.

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	_	NON PATENT LITERATURE DOCUMENTS	
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		Wilson, G.S., and A.A. Miles, "Tuberculosis." Chap. 59 in Topley and Wilson's Principles of Bacteriology and Immunity. 4th ed. 2 vols. London: Edward Arnold (Publishers Ltd. (1955).	
		L. De Wit, et al., "Nucleotide sequence Mycobacterium bovis BCG," 1990, 18(13):3995, Nucleic Acids Research.	
		De Wit, Luk, et al., "Nucleotide Sequence of the 85B-Protein Gene of Mycobacterium bovis BCG and Mycobacterium tuberculosis," DNA Sequence, vol. 4, No. 4, 1994, pp. 267-270.	
		A. Worsaae et al., "Allergenic and Blastogenic Reactivity Guinea Pigs," Dec. 1987, 55(12):2922-2927, Infection and Immunity.	
		Yamaguchi, Ryuji, et al., "Cloning and Characterization of the Immunogenic Protein MPB64 of Mycobacterium bovis BCG," Infection and Immunity, vol. 57, No. 1, Jan. 1989, pp. 283-288.	
		Yanisch-Perron, C., et al. "Improved M13 Phage Cloning Vectors and Host Strains: Nucleotide Sequences of the M13mp18 and pUC19 Vectors." Gene 33 (1985) 103-19.	
		Youmans, G.P. "Acquired Immunity in Tuberculosis." Chap. 8 in Tuberculosis. Edited by G.P. Youmans Philadelphia: The W.B. Saunders Co. (1979).	
		R.A. Young et al., "Dissection of Mycobacterium tuberculosis antigens using recombinant DNA," May 1985, 82:2583-2587, Proc. Natl. Acad. Sci. USA.	
		D. Young et al., "Immunological Activity Mycobacterium tuberculsis," Oct. 1986, 177-183, Infection and Immunity, vol. 54, No. 1.	
		D. Young et al., "Stress proteins are immune targets in leprosy and tuberculosis," Jun. 1988, 85:4267-4270, Proc. Natl. Acad. Sci.	
		Young, D.B., et al. "Mycobacterial Protein Antigens: A Compilation." Mol. Micro. 6 (2):133-45. (1992)	
		Young, Douglas B., and Angela Mehlert. "Serology of Mycobacteria: Characterization of Antigens Recognized by Monoclonal Antibodies." Reviews of Infectious Disease, 1989, 11(2): S431-5.	
		Zhang, Y. et al., "Genetic analysis of superoxide dismutase, the 23 kilodalton antigen of Mycobacterium tuberculosis," Mol. Microbiol. 1991, vol. 5(2), 381-391.	
		"Use of BCG Vaccines : A Joint Statement by the ACIP and the Adv'y Comm. for Elim. of Tuberculosis," Nov. 4, 1988, 37(43):663-675, MMWR.	

Examiner	Date	
Signature	Considered	

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